

## IN THE UNITED STATES RECEIVING OFFICE

Applicant : Craig Gregory Smith, et al. Conf. No.: 9329  
Serial No.: 10/508,398  
Filed : September 20, 2004  
Title : MANAGEMENT CONTROL OF PHARMACEUTICAL SUBSTANCES

**Mail Stop PCT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS

Responsive to the Notification of Missing Requirements  
under 35 U.S.C. 371 mailed April 19, 2005, Applicants as a small  
entity submit herewith the following:

- ☒ Payment of the surcharge of \$65 for late filing of the  
declaration;
- ☒ A check in the total amount of \$65 is attached;
- ☒ A Combined Declaration and Power of Attorney in  
compliance with 37 CFR §1.63 (2 pages);
- ☒ A copy of check no. 183446 in the amount of \$712  
(1 page); and
- ☒ A copy of the Transmittal Letter Concerning Filing  
Under 35 U.S.C. 371 (2 pages).

Applicants submit that the filing fees and fees for  
additional claims and multiple dependent claims, a total of 23  
claims, were submitted with the application on September 20,

05/16/2005 GFREY1 00000071 10508398

01 FC:2617

65.00 OP

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EV471530585USMay 10, 2005

Date of Deposit

Applicant : Craig Gregory Smith et al.  
Serial No. : 10/508,398  
Filed : September 20, 2004  
Page : 2 of 2

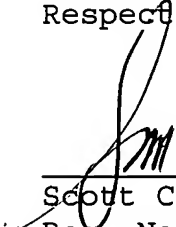
Attorney's Document No.: 18155-002US1 / 117961

2004. Enclosed is a copy of the application transmittal and check no. 183446. No additional fees are believed to be due.

It is understood that this perfects the application and no additional papers or filing fees are required. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: May 10, 2005

  
\_\_\_\_\_  
Scott C. Harris  
Reg. No. 32,030

Fish & Richardson P.C.  
PTO Customer No. **20985**  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (619) 501-5091  
Facsimile: (858) 678-5099

10513437.doc



UNITED STATES PATENT AND TRADEMARK OFFICE

Rec'd PCT/PTO 10 MAY 2005

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
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Alexandria, Virginia 22313-1450  
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Sett

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/508,398	Craig Gregory Smith	18155-002US1

INTERNATIONAL APPLICATION NO.
PCT/AU04/00150

20985  
FISH & RICHARDSON, PC  
12390 EL CAMINO REAL  
SAN DIEGO, CA 92130-2081

DOCKETED BY PRACTICE SYSTEMS
ACTION CODE: <u>PCT MISSING REQ</u>
BASE DATE: <u>4/19/05</u>
DUE DATE: <u>4/19/05</u>
DEADLINE: <u>11/19/05</u>
INITIALS: <u>CM</u>
RECORD:

LA. FILING DATE	PRIORITY DATE
02/11/2004	02/11/2003

CONFIRMATION NO. 9329  
371 FORMALITIES LETTER  
OC000000015773279\*

Date Mailed: 04/19/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 09/20/2004
- Copy of the International Search Report filed on 09/20/2004
- Preliminary Amendments filed on 09/20/2004
- Information Disclosure Statements filed on 09/20/2004
- Small Entity Statement filed on 09/20/2004
- U.S. Basic National Fees filed on 09/20/2004
- Priority Documents filed on 09/20/2004

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APR 22 2005

FISH & RICHARDSON, P.C.  
SAN DIEGO

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$150 as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$150 for a Small Entity

Docketed By Billing Secretary
Due Date: <u>6/19/05</u>
Deadline: <u>11/19/05</u>
Initials: <u>GR</u>

• Total additional claim fee(s) for this application is \$ 150

- \$150 for 9 total claims over 20.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

DARRELL C COTTMAN

Telephone: (703) 308-9140 EXT 203

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/508,398	PCT/AU04/00150	18155-002US1

FORM PCT/DO/EO/905 (371 Formalities Notice)

Rec'd PCT/PTO 10 MAY 2005

Attorney's Docket No. 18155-002US1	Express Mail Label No. EV398158922US	Mailing Date September 20, 2004
Applicant Not yet assigned	Filing Date September 20, 2004	Attorney/Secretary Init SCH/jhp

*For PTO Use Only  
Do Not Mark in This Area*

Title of the Invention  
**MANAGEMENT CONTROL OF PHARMACEUTICAL  
SUBSTANCES**

Applicant  
**Craig Gregory Smith, et al.**

Client Reference No.  
117961

Enclosures

- Transmittal Letter (2 pages)
- Patent Application (12 pages of specification, 6 pages of claims, 23 total claims, 1 page of abstract)
- Check in the amount of \$712.00
- Drawings (formal, 2 sheets)
- Preliminary Amendment (12 pages)
- Information Disclosure Statement (2 pages)
- Form PTO-1449 (2 pages)
- Documents listed on the Form PTO-1449 (20 documents)
- Copy of International Search Report (4 pages)

**FR FISH & RICHARDSON P.C.**

225 Franklin Street  
Boston, Massachusetts  
02110-2804

c 183446

PAY Seven hundred twelve dollars 00/100 DOLLARS

TO THE ORDER OF	DATE	AMOUNT
COMMISSIONER OF PATENTS AND TRADEMARKS	09/20/04	\$712.00

18155-002US1 jhp

FISH & RICHARDSON P.C.

52-153/112



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Fleet Maine, N.A.  
www.fleet.com  
South Portland, ME

BY

*[Signature]*

⑈ 183446 ⑈ ⑆ 011201539⑆ 80 071 123 ⑈

SUBSTITUTE FORM PTO-1390

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

18155-002US1

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

INTERNATIONAL APPLICATION NO.  
PCT/AU2004/000150

INTERNATIONAL FILING DATE  
11 February 2004

PRIORITY DATE CLAIMED  
11 February 2003

TITLE OF INVENTION  
MANAGEMENT CONTROL OF PHARMACEUTICAL SUBSTANCES

APPLICANT(S) FOR DO/EO/US  
Craig Gregory Smith and Robert Richards

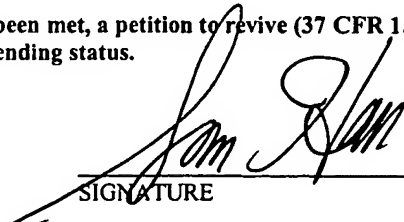
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11 to 20 below concern document(s) or information included:**

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:  
Copy of International Search Report

**CERTIFICATE OF MAILING BY EXPRESS MAIL**  
Express Mail Label No. EV398158922US  
Date of Deposit: September 20, 2004

U.S. APPLICATION NO. (if known, see 37 CFR 1.53)		INTERNATIONAL APPLICATION NO. PCT/AU2004/000150		ATTORNEY'S DOCKET NUMBER 18155-002US1	
21. <input checked="" type="checkbox"/> The following fees are submitted:  <b>Basic National Fee ( 37 CFR 1.492 (a) (1) - (5)):</b>  Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO..... \$1080  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO..... \$920  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO..... \$770  International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)..... \$730  International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)..... \$100  <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>				<b>CALCULATIONS PTO USE ONLY</b>	
				\$1,080.00	
				\$0.00	
Surcharge of \$130 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	23 - 20 =	3	x \$18	\$54.00	
Independent Claims	2 - 3 =	0	x \$86	\$0.00	
MULTIPLE DEPENDENT CLAIMS(S) (if applicable)			+ \$290	\$290.00	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$1,424.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$712.00	
<b>SUBTOTAL =</b>				\$712.00	
Processing fee of \$130 for furnishing the English Translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f))				\$0.00	
<b>TOTAL NATIONAL FEE =</b>				\$712.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$0.00	
<b>TOTAL FEES ENCLOSED =</b>				\$712.00	
				Amount to be refunded:	\$
				charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$712.00 to cover the above fees is enclosed.  b. <input type="checkbox"/> Please charge my Deposit Account No. 06-1050 in the amount of \$0.00 to cover the above fees. A duplicate copy of this sheet is enclosed.  c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1050. A duplicate copy of this sheet is enclosed.					
<b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:					
PTO Customer No: 20985		 SIGNATURE			
		NAME Scott C. Harris			
		REGISTRATION NUMBER 32,030			